IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

UNITED STATES OF AMERICA Plaintiff,	§	CRIMINAL NO. H-07-100
	§	18 U.S.C. § 371
	§	18 U.S.C. § 1341
v.	§	18 U.S.C. § 1001
	§	21 U.S.C. § 331(k), 333(a)(2)
GAYLE ROTHENBERG	§	18 U.S.C. § 981(a)(1)(c)
SAUL GOWER	§	28 U.S.C. § 2461(c)
Defendants.		

INDICTMENT

UNITED STATES COURTS
SOUTHERN DISTRICT OF TEXAS
FILED

MAR 21 2007

MICHAEL N. MILBY, CLERK OF COURT

THE GRAND JURY CHARGES:

COUNT ONE
(Conspiracy – 18 U.S.C. § 371, 1349)

Introduction

At all times material to this indictment:

1. Defendant Gayle Rothenberg, M.D. was licensed by the Texas State Board of Medical Examiners for the State of Texas as a medical doctor with a specialty in the area of Anesthesiology.

2. Defendant Gayle Rothenberg, M.D. operated a medical practice located at 2000 Bering Drive, Suite 260, Houston, Texas under the name "CENTER FOR IMAGE ENHANCEMENT."

3. Defendant Gayle Rothenberg devoted the majority of her medical practice to performing procedures such as Botox injections, Collagen injections, Microdermabrasion, PhotoFacial, Restylane, etc. to enhance the physical appearance of her patients.

4. Defendant Saul Gower was the office manager at the "CENTER FOR IMAGE

ENHANCEMENT" and the husband of defendant Gayle Rothenberg. Defendant Gower was responsible for the overall operation of the clinic including the payment of invoices for supplies and materials.

5. Toxin Research International, Inc. ("TRI") was an Arizona corporation, with its principal place of business in Tucson, Arizona. TRI's articles of incorporation identified Chad Livdahl and Zahra Karim as the corporation's initial board of directors and described TRI's business as "toxin distribution and research."

6. During 2004, TRI sold a Botulinum Toxin Type A substance to physicians, which was not approved or licensed by the FDA for use on humans. This substance was sold in injectable vials which were labeled, "FOR RESEARCH PURPOSES ONLY, NOT FOR HUMAN USE.

7. Beginning in or about February 2004 and continuing through November 2004, defendants Gayle Rothenberg and Saul Gower defrauded approximately one hundred seventy (170) patients who received injections intended to reduce facial wrinkles. As more particularly described below, Rothenberg and Gower defrauded patients by representing that they were receiving injections of FDA approved Botox® (Botulinum Toxin Type A), when in fact patients received injections of a Botulinum Toxin Type A substance which was not approved by the FDA for use on humans and which bore the statement "FOR RESEARCH PURPOSES ONLY, NOT FOR HUMAN USE" on its labeling, packaging and invoices.

Botulinum Toxin Type A

8. The United States Food and Drug Administration ("FDA") is the agency of the United States charged with the responsibility of protecting the health and safety of the American public by enforcing the Federal Food, Drug and Cosmetic Act, Title 21, United States Code,

Sections 301, *et seq*.. (the "FDCA"). One purpose of the FDCA is to ensure that drugs sold for consumption or administration to humans are safe, effective, and bear labeling containing only true and accurate information. The FDA's responsibilities under the FDCA include regulating the manufacture, labeling, and distribution of all drugs, drug components and biological products shipped or received in interstate commerce.

9. The FDA enforces drug safety and efficacy standards by guarding against the misbranding of drugs. The FDCA prohibit, among other things, the doing of any act with respect to a drug if such act is done while the drug is held for sale after shipment in interstate commerce, and results in the drug being misbranded. 21 U.S.C. § 331(k). A drug is misbranded if, among other things, it is offered for sale under the name of another drug. 21 U.S.C. § 352(i)(3).

10. Botulinum Toxin Type A is a drug. The term "drug" as used in the FDCA includes articles recognized in the official United States Pharmacopoeia; articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man; and articles intended to affect the structure of any function of the body of man. 21 U.S.C. § 321(g)

11. Botulinum Toxin Type A is also a biological product. The term "biological product" includes viruses, toxins, blood, and other specific similar substances applicable to the prevention, treatment, or cure of a disease or condition of human beings. 42 U.S.C. § 262(I).

12. Many products meet the definitions of both drugs and biological products. Pursuant to 21 U.S.C. § 262(j), the Act applies to biological products subject to regulation under Title 42, except that a product for which a biological license has been approved under subsection 42 U.S.C. § 262(a) is not required to have an approved new drug application under 21 U.S.C. § 355.

13. The term "new drug" was defined by 21 U.S.C. § 321(P), as any drug not generally

recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs for use under the conditions prescribed, recommended or suggested in its labeling.

14. A new drug which is also a biological product cannot lawfully be entered into interstate commerce unless there is a biological license in effect or there is in effect with the FDA a new drug application, an abbreviated new drug application, or a notice of claimed exemption for an investigational new drug.

15. The bacterium *Clostridium Botulinum* produces Botulinum Toxin Type A, a highly potent toxin that can be dangerous and cause the disease botulism when present in sufficient amounts in human beings.

16. Botulism is a muscle-paralyzing condition in which Botulinum Toxin Type A binds to nerve endings at the point where nerves join muscles, preventing the nerves from signaling the muscles to contract. Botulism can result in weakness and paralysis that severely affects, among other things, the muscles that control breathing. Severe botulism generally results in death, unless the patient receives proper care to ensure continued breathing. Recovery occurs when the affected nerves grow new endings, a process that can extend over several months, although recovery time varies greatly from case to case.

Allergan Botox® and Botox® Cosmetic

17. On or about December 9, 1991, the Food and Drug Administration ("FDA") approved Botox®, a drug derived from Botulinum Toxin Type A and manufactured by Allergan Inc., of Irvine, California, for the treatment of certain medical conditions in human beings.

18. On or about April 12, 2002, the FDA approved a supplement to Allergan's Botox® license application for the treatment of glabellar lines, commonly referred to as forehead

wrinkles. Under this FDA approval, Allergan's Botulinum Toxin Type A product was marketed and labeled for the supplemental usage as Botox® Cosmetic.

19. Allergan's Botox® and Botox® Cosmetic constitute the only drugs containing Botulinum Toxin Type A approved by the FDA for use in human beings.

THE CONSPIRACY

20. Beginning in or about January, 2004 and continuing thereafter to in or about February 2005, in the Houston Division of the Southern District of Texas and elsewhere, defendants,

GAYLE ROTHENBERG,
SAUL GOWER,

did knowingly and willfully combine, conspire and confederate and agree with each other and other persons unknown to the grand jury to commit certain offenses against the United States, namely:

a To use the Postal Service or commercial or private interstate carrier of mail matter in furtherance of a scheme and artifice to defraud violation of Title 18, United States Code, Section 1341.

b. To violate the Food, Drug and Cosmetic Act, namely, with the intent to defraud and mislead, causing a drug to be misbranded by offering a drug for sale under the name of another drug after being shipped in interstate commerce, in violation of Title 21, United States Code, Section 331(k) and 352(i)(3).

OBJECT OF THE CONSPIRACY

21. It was the object of the conspiracy for the defendants and others to unlawfully enrich themselves by falsely representing to patients that they were receiving injections of FDA approved Botox® and Botox® Cosmetic manufactured and marketed by Allergan Corporation when in fact patient's received injections of a TRI Botulinum Toxin Type A substance which was not FDA approved for use on humans and which bore the labeling "FOR RESEARCH PURPOSES ONLY, NOT FOR HUMAN USE." As a result of this fraudulent scheme, defendants were paid over $98,000.00 in fees from patients for these treatments. The defendants never disclosed to these patients prior to the treatments that the substance with which they were injected had not been approved by the FDA and was not genuine Botox® and Botox® Cosmetic, but in fact was the non-FDA approved TRI-botulinum toxin.

MANNER AND MEANS

The manner and means of the conspiracy included, but were not limited to the following:

22. Defendant GAYLE ROTHENBERG would and did offer and advertise Allergan's Botox® and Botox® Cosmetic injections and treatment at her clinic, CENTER FOR IMAGE ENHANCEMENT.

23. Defendant GAYLE ROTHENBERG would and did display Botox® and Botox® Cosmetic brochures and other promotional materials to promote these FDA approved products in the lobby of the CENTER FOR IMAGE ENHANCEMENT clinic.

24. Defendant GAYLE ROTHENBERG would and did advertise Botox® and Botox® Cosmetic procedures on her website www.drgayle.com and in local magazines including "NU IMAGE."

25. Defendant GAYLE ROTHENBERG would and did stop ordering Botox® and

Botox® Cosmetic products from Allergen in February 2004 because of a price increase and began ordering non-FDA approved TRI-botulinum toxin.

26. Defendant GAYLE ROTHENBERG would and did continue to order TRI-botulinum toxin through September 2004 and did not order any Botox® and Botox® Cosmetic products from Allergan during this time period.

27. Defendant GAYLE ROTHENBERG would and did use TRI-botulinum toxin on patients even though the labeling on the TRI-botulinum toxin vial, packaging and product safety information stated "FOR RESEARCH PURPOSES ONLY, NOT FOR HUMAN USE."

28. Defendant GAYLE ROTHENBERG would and did have patients to sign an "Inform Consent for Botox® Injection Therapy" form and fraudulently represented that she intended to use FDA approved Botox® when in fact the defendant intended to use and did use non-approved TRI-botulinum toxin on patients.

29. Defendant GAYLE ROTHENBERG would and did fail to inform patients that she was using non-FDA approved TRI-botulinum toxin when performing injections to reduce facial wrinkles.

30. Defendant GAYLE ROTHENBERG would and did order 20 vials containing TRI-botulinum toxin for use on over 170 patients.

31. Defendant SAUL GOWER would and did approve the use of TRI-botulinum toxin on patients even though he knew all material accompanying the product stated "FOR RESEARCH PURPOSES ONLY, NOT FOR HUMAN USE."

32. Defendant SAUL GOWER would and did falsely represent to agents with the FDA that the TRI-botulinum toxin had not been used on patients when he well knew patients had received injections of the non-approved product from February 2004 through September 2004.

33. Defendant GAYLE ROTHENBERG would and did falsely represent to agents with the FDA that the TRI-botulinum toxin had not been used on patients when she well knew patients had received injections of the non-approved product.

34. Defendant GAYLE ROTHENBERG would and did fail to record in the patient's file, the lot number and expiration date of the non-approved TRI substance used in performing injections to reduce facial wrinkles but instead indicated the substance that had been used was Botox.

OVERT ACTS

35. In furtherance of the conspiracy and to effect the objects thereof, the following Overt Acts, among others, were committed in the Southern District of Texas.

(1) In or about February, 2004, defendants GAYLE ROTHENBERG and SAUL GOWER returned from a conference and told the staff at the CENTER FOR IMAGE ENHANCEMENT that they had discovered a new Botox product that would be used on patients.

(2) On February 3, 2004, defendant GAYLE ROTHENBERG directed her staff to begin ordering botulinum toxin from TRI.

(3) On February 3, 2004, defendant GAYLE ROTHENBERG caused one of her employees to order 2 vials, each containing 500 IU of botulinum toxin from TRI which was sent "UPS Overnight Cold Shipping." The price of the 2 vials was $ 2,041.25. The invoice accompanying the vials stated "FOR RESEARCH PURPOSES ONLY, NOT FOR HUMAN USE."

(4) On February 19, 2004, defendant GAYLE ROTHENBERG met with patient C.P. to discuss Botox Injection Therapy after the patient had read and signed a form indicating that Botox® would be used.

(5) On February 19, 2004, defendant GAYLE ROTHENBERG performed injections on patient C.P. using TRI-botulinum toxin instead of FDA approved Botox® and Botox® Cosmetic.

(6) On March 1, 2004, defendant GAYLE ROTHENBERG caused one of her employees to order 2 vials, each containing 500 IU of botulinum toxin from TRI which was sent "UPS Overnight Cold Shipping." The price of the 2 vials was $ 2,041.25. The invoice accompanying the vials stated "FOR RESEARCH PURPOSES ONLY, NOT FOR HUMAN USE."

(7) On March 4, 2004, defendant GAYLE ROTHENBERG performed injections using TRI-botulinum toxin on patient L.C. instead of FDA approved Botox® and Botox® Cosmetic.

(8) On March 16, 2004, defendant SAUL GOWER, reviewed the invoice dated March15, 2004 and confirmed the purchase of botulinum toxin from TRI.

(9) On April 7, 2004, defendant GAYLE ROTHENBERG caused one of her employees to order 2 vials, each containing 500 IU of botulinum toxin from TRI which was sent "UPS Overnight Cold Shipping." The price of the 2 vials was $ 2,041,25. The invoice accompanying the vials stated "FOR RESEARCH PURPOSES ONLY, NOT FOR HUMAN USE."

(10) On April 21, 2004, defendant GAYLE ROTHENBERG performed injections on patient A.L. using TRI-botulinum toxin instead of FDA approved Botox® and Botox® Cosmetic.

(11) On August 16, 2004, defendant GAYLE ROTHENBERG caused one of her employees to order 2 vials, each containing 500 IU of botulinum toxin from TRI which was sent "UPS Overnight Cold Shipping." The price of the 2 vials was $ 2,041.25. The invoice accompanying the vials stated "FOR RESEARCH PURPOSES ONLY, NOT FOR HUMAN USE."

(12) On August 17, 2004, defendant SAUL GOWER, reviewed the invoice dated

March15, 2004 and confirmed the purchase of botulinum toxin from TRI.

(13) On August 26, 2004, defendant GAYLE ROTHENBERG performed injections using TRI-botulinum toxin on patient T.B. instead of FDA approved Botox® and Botox® Cosmetic.

(14) On January 20, 2005, defendant GAYLE ROTHENBERG falsely represented to agents with the Food and Drug Administration that she had only used Botox® on her patients.

(15) On January 20, 2005, defendant SAUL GOWER falsely represented to agents with the Food and Drug Administration that defendant Gayle Rothenberg had only used Botox® on her patients.

In violation of Title 18, United States Code, Sections 371 and 1349.

COUNTS TWO THROUGH ELEVEN
(Mail Fraud-Using non-FDA approved drugs)
(18 U.S.C. § 1341)

1. The Grand Jury realleges paragraphs 1 through 19 and 22 through 32 of Count One above and incorporates them as if alleged herein.

EXECUTION OF THE SCHEME

2. On or about the dates listed below, in the Southern District of Texas and elsewhere, the defendants,

GAYLE ROTHENBERG,
SAUL GOWER,

intentionally and knowingly and for the purpose of executing and attempting to execute the scheme and artifice to defraud, and obtaining money and property by means of materially false and fraudulent pretenses, representations and promises described above, did knowingly cause vials of TRI-botulinum toxin, to be delivered by mail or private or commercial interstate carrier,

specifically by United Parcel Service (UPS), from TRI in Arizona, to the Center for Image Enhancement located at 2000 Bering Drive, Suite 260, Houston, Texas 77057, according to the directions thereon, as more specifically described below:

COUNT	DATE OF SHIPMENT BY UPS (on or about)	PRODUCT ORDERED	PRODUCT SHIPPED FROM	PRODUCT SHIPPED TO
2	2/3/2004	2 vials containing Stabilized Botulinum Toxin Type A: 500 IU	TRI-Toxin Research International, Tucson, AZ	Dr. Gayle Rothenberg, M D Houston, TX
3	3/1/2004	2 vials containing Stabilized Botulinum Toxin Type A: 500 IU	TRI-Toxin Research International, Tucson, AZ	Dr. Gayle Rothenberg, M D Houston, TX
4	3/15/2004	2 vials containing Stabilized Botulinum Toxin Type A: 500 IU	TRI-Toxin Research International, Tucson, AZ	Dr. Gayle Rothenberg, M D Houston, TX
5	4/7/2004	2 vials containing Stabilized Botulinum Toxin Type A: 500 IU	TRI-Toxin Research International, Tucson, AZ	Dr. Gayle Rothenberg, M D Houston, TX
6	5/4/2004	2 vials containing Stabilized Botulinum Toxin Type A: 500 IU	TRI-Toxin Research International, Tucson, AZ	Dr. Gayle Rothenberg, M D Houston, TX
7	6/7/2004	2 vials containing Stabilized Botulinum Toxin Type A: 500 IU	TRI-Toxin Research International, Tucson, AZ	Dr. Gayle Rothenberg, M D Houston, TX
8	7/6/2004	2 vials containing Stabilized Botulinum Toxin Type A: 500 IU	TRI-Toxin Research International, Tucson, AZ	Dr. Gayle Rothenberg, M D Houston, TX

9	8/3/2004	2 vials containing Stabilized Botulinum Toxin Type A: 500 IU	TRI-Toxin Research International, Tucson, AZ	Dr. Gayle Rothenberg, M D Houston, TX
10	8/16/2004	2 vials containing Stabilized Botulinum Toxin Type A: 500 IU	TRI-Toxin Research International, Tucson, AZ	Dr. Gayle Rothenberg, M D Houston, TX
11	9/8/2004	2 vials containing Stabilized Botulinum Toxin Type A: 500 IU	TRI-Toxin Research International, Tucson, AZ	Dr. Gayle Rothenberg, M D Houston, TX

In violation of Title 18, United States Code, Sections 2, 1341 and 1349.

COUNT TWELVE
(Misbranding of a Drug While Held for Sale)
(21 U.S.C. § 331(k))

1. The allegations contained in the preceding paragraphs 1 through 19 and 22 through 32 are incorporated by reference as though set forth fully herein.

2. On or about February 2004 through November, 2004, in the Southern District of Texas and elsewhere, the defendants,

GAYLE ROTHENBERG,
SAUL GOWER,

with the intent to defraud and mislead, misbranded a drug, namely Botulinum Toxin Type A distributed by Toxin Research International, Inc. while it was held for sale and after shipment in interstate commerce, in that the defendants offered the TRI Botulinum Toxin Type A for sale for injection therapy to patients under the name of another drug, namely Botox®, which the defendants then and there knew to be an FDA-approved drug sold by Allergan under the name of

Botox® and Botox® Cosmetic.

In violation of 21 U.S.C. § 331(k), 21 U.S.C. § 333(a)(2), 21 U.S.C. § 352(i)(3) and 18 U.S.C. § 2.

COUNT THIRTEEN
(False Statement)
(18 U.S.C. § 1001)

1. On or about January 20, 2005, in the Southern District of Texas and elsewhere, the defendant,

GAYLE ROTHENBERG,

did intentionally and knowingly, in a matter within the jurisdiction of the Food and Drug Administration, an agency of the United States Government, make a materially false and fraudulent statement and representation, namely, that she did not have any TRI related materials, including paperwork from TRI when asked if she had such materials by agents with the Food and Drug Administration when she well knew that she had in her possession TRI invoices and product information and the purpose for making such a statement was to mislead the FDA regarding the use of a non-FDA approved substance.

In violation of Title 18, United States Code, Section 1001.

COUNT FOURTEEN
(False Statement)
(18 U.S.C. § 1001)

1. On or about January 20, 2005, in the Southern District of Texas and elsewhere, the defendant,

SAUL GOWER,

did intentionally and knowingly, in a matter within the jurisdiction of the Food and Drug Administration, an agency of the United States Government, make a materially false and fraudulent statement and representation, namely, that TRI Botulinum Toxin Type A had only been

used on friends and staff members, and that patients had received genuine Botox® and Botox® Cosmetic when he well knew that the TRI product had been used on patients and the purpose of making such a statement was to mislead the FDA regarding the use of a non-FDA approved substance.

In violation of Title 18, United States Code, Section 1001.

NOTICE OF CRIMINAL FORFEITURE

The allegations of Counts One (1) through Eleven (11) of this Indictment are re-alleged and by this reference fully incorporated herein for the purpose of alleging forfeitures to the United States of America of property, in which one or more of the defendants has an interest, pursuant to the provisions of Title 28, United States Code, Section 2461 and Title 18, United States Code, Section 981(a)(1)(c).

Pursuant to Title 18, United States Code, Sections 981(a)(1)(c) and Title 28, United States Code, Section 2461, as a result of the commission of conspiracy as charged in Count One (1) of the Indictment and mail fraud as charged in Counts Two (2) through Eleven (11) of the Indictment, notice is given that the defendants, Gayle Rothenberg and Saul Gower, shall forfeit to the United States all property, real or personal, which constitutes or is derived from proceeds traceable to the commission of the above offenses as charged in the Indictment, including, but not limited to, a money judgment for the full amount of the proceeds traceable to such violations.

In the event that the property which is subject to forfeiture to the United States, as a result of any act or omission of the defendant:

i. cannot be located upon exercise of due diligence;

ii. has been placed beyond the jurisdiction of the Court;

iii. has been transferred or sold to, or deposited with a third party;

iv. has been substantially diminished in value; or

v. has been commingled with other property which cannot be divided without difficulty;

it is the intent of the United States to seek forfeiture of any other property of the defendant up to the value of such property, pursuant to Title 21, United States Code, Section 853(p), made applicable to these offenses by Title 18, United States Code, Section 982(b).

A TRUE BILL

Original Signature on File

DONALD J. DeGABRIELLE, JR.
UNITED STATES ATTORNEY

By: Samuel Louis

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